REMARKS

Claims 74 and 76-84 are pending and examined in this application.

Claims 74 and 76-80 have been amended to recite that the claimed recognition molecule is "recombinant." Support for this amendment is found throughout the specification and the Examples. Claims 76, 79 and 82 have been amended to correct inadvertent typographical errors. Claim 81 has been amended to incorporate the limitations of previous claim 74, from which claim 81 depended. No new matter has been added by these amendments and entry thereof is respectfully requested.

I. The Rejection Under 35 U.S.C. § 102(b) Should be Withdrawn

Claims 74, 77, 78 and 79 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Karsten, *Hybridoma*, 1995, 14:37-44 ("Karsten"). Applicants respectfully traverse this rejection.

The claims encompass, *inter alia*, a recombinant recognition molecule comprising variable heavy (VH) and variable light (VL) antibody framework sequences and complementarity determining regions (CDRs) comprising the amino acid sequences set forth in (i) the amino acid sequence SEQ ID NO. 1, (ii) the amino acid sequences SEQ ID NO. 2 or 3, (iii) the amino acid sequence SEQ ID NO. 4, 5 or 6, (iv) the amino acid sequence SEQ ID NO. 7 or 8 or 9, (v) the amino acid sequence SEQ ID NO. 10 or 11, and (vi) the amino acid sequence SEQ ID NO. 12 or 13, and which specifically binds to the core 1 antigen.

According to the Office Action, Karsten allegedly discloses a "monoclonal antibody which specifically binds both anomeric forms of the TF alpha and TF beta antigens, which is the same binding specificity as indicated in the instant specification on page 6, lines 16-18." (Office Action at p. 2.) The Office Action admits that Karsten does not "teach that the antibody has the same hypervariable regions as the instant recognition molecule," but the Examiner states that the molecules appear to be "the same in terms of epitope binding absent a showing of unobvious differences." *Id*.

Applicants submit that Karsten does not disclose each and every element of the presently claimed invention. The disclosure of a monoclonal antibody that "specifically binds both anomeric forms of the TF alpha and TF beta antigens, which is the same binding specificity as

indicated in the instant specification," as asserted in the Office Action, is not a *recombinant* recognition molecule. The disclosure of the existence of a monoclonal antibody, without specific information regarding the structure and amino acid sequence of the antibody, cannot anticipate a claim directed to a recombinant recognition molecule comprising the recited amino acid sequences. Thus, Karsten cannot and does not anticipate the presently claimed invention. *See* M.P.E.P. § 2131.

Moreover, Applicants respectfully submit that Karsten would not have enabled a skilled artisan to make or use the claimed recombinant recognition molecules. The Federal Circuit has explained that anticipation requires that a prior art reference must enable one of ordinary skill in the art to make the claimed invention without undue experimentation. *See Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.* (545 F.3d 1312 (Fed. Cir. 2008) (citing *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008).

Applicants respectfully submit that the disclosure of a monoclonal antibody does not enable one of ordinary skill in the art to make and use the presently claimed recombinant recognition molecules. Karsten provides no disclosure of the structure of the monoclonal antibody, let alone the amino acid sequence of the antibody. Applicants submit, absent this information, one of ordinary skill in the art would have needed to undertake undue experimentation to make and use the specific recombinant recognition molecules of the presently claimed invention. Applicants also respectfully submit that, absent a showing of the structure and sequence of the monoclonal antibody, a person of ordinary skill in the art would not have had a reasonable expectation of success of preparing the presently claimed recombinant recognition molecules, based on the disclosure of Karsten.

Furthermore, as stated in Applicants' Reply to Office Action dated July 20, 2009, the Office Action has made no showing that the hybridoma in Karsten was publicly available. Simply asserting that "it is unclear if Karsten et al have made the antibody publicly available via personal requests," (*see* Office Action at page 3) is not sufficient to show that the antibody was in fact available as prior art to the presently claimed invention.

Based on at least the arguments set forth above, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

II. Objection to Dependent Claims should be withdrawn

Claims 76 and 80-84 are objected to as being dependent upon a rejected base claim. The Office Action indicates that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants respectfully submit that the rejection under 35 U.S.C. § 102(b) has been overcome as discussed above, and thus claims 76, 80 and 84 are allowable.

Claims 81-83 have been amended to incorporate the limitations of previous claim 74, and thus, as indicated in the Office Action, Applicants believe that these claims are in condition for immediate allowance.

III. Conclusion

Applicants believe that the claims are in condition for allowance and respectfully request allowance thereof. The Examiner is invited to telephone the undersigned if that would be helpful in resolving any issues.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-5071.

Respectfully submitted,

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